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June 11, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Subject: Docket No. 99N-0035 "Medical Devices; Reclassification of 38 Preamendments Class III Devices Into Class II"

To Whom It May Concern:

This letter is being written on behalf of Radiometer Medical A/S to request an extension for 60 days for the submission of comments with respect to the reclassification of cutaneous oxygen monitors, 868.2500 as described in the aforementioned Docket.

This extension is being requested to allow for the completion and translation of analysis of proposed compliance standards, comments on the reclassification and supporting documentation. The supporting information being collected cannot be completed until early August. Nevertheless, Radiometer will provide their comments as soon as possible.

We would appreciate your careful consideration of this request.

Sincerely,

James M Howard

James M. Howard, II
Senior Vice President
Bio-Reg Associates, Inc.

DTB

cc: Joseph Sheehan

99N-0035

EXT 1

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